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PATENT
Atty. Docket No.:
CIBT-P10-203

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In re Application of: Scott et al.

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Serial No.: 09/754,032

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Group Art Unit: 1646

Filed: 03-Jan-2001

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Examiner: Not Yet Assigned

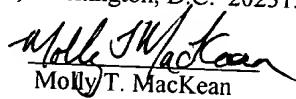
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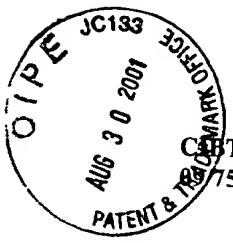

Molly T. MacKean

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INFORMATION DISCLOSURE STATEMENT UNDER 37C.F.R. 1.97(b)

Submitted herewith on Form PTO-1449 is a list of documents known to Applicants, their Agent and/or Attorney in compliance with the requirements of 37 C.F.R. 1.56. A copy of each document listed is also being submitted herewith.

This Information Disclosure Statement is being filed before the mailing of the first office action on the merits; therefore, no fee is due.



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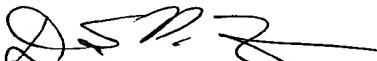
Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached Form PTO-1449.

This submission does not represent that a search has been made or that no better art exists. Nor does it constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there are any fees due in connection with the filing of this Statement, please charge the fees to our **Deposit Account, No. 18-1945**.

Respectfully submitted,
Ropes & Gray

By: 

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**INFORMATION DISCLOSURE CITATION
IN AN APPLICATION**
JC133 (Use several sheets if necessary)
Docket Number (Optional)
CIBT-P10-203Application Number
09/754,032**RECEIVED**
Sheet Page 1 of 6Applicant
Scott et al.Filing Date
03-Jan-2001Group Art
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U.S. PATENT DOCUMENTS						
EXAMINER INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
PTENKA	5798209	25-Aug-1998	Chan	435	6	26-May-1995
AB	5837538	17-Nov-1998	Scott	435	325	06-Oct-1995
AC	5935810	10-Aug-1999	Friedman et al.	435	69.1	30-Nov-1994
FOREIGN PATENT DOCUMENTS						
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation YES NO
AD	WO9611260	18-Apr-1996	PCT	C12N	5/00	
OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages Etc.)</i>						
AE	Akimaru, H. et al., "Drosophila CBP is a co-activator of cubitus interruptus in hedgehog signaling", Nature 386 (6626): 735-738 (1997).					
AF	Akiyama, H. et al., "Cloning of a mouse smoothened cDNA and expression patterns of hedgehog signaling molecules during chondrogenesis and cartilage differentiation in conal mouse EC cells, ATDC5", Biophys Res. Comm., 235(1): 142-147 (1997).					
AG	Alberts, eds., Molecular Biology of the Cell, G-10 (1994).					
AH	Alcedo, J. et al., "The Drosophila smoothened gene encodes a seven-pass membrane protein, a putative receptor for the hedgehog signal", Cell, 86 (2): 221-232 (1996).					
AI	Alcedo, J. and Noll, M., "Hedgehog and its patched-smoothened receptor complex: a novel signaling mechanism at the cell surface", Biol. Chem., 378 (7): 583-590 (1997).					
AJ	Alexandre, C. et al., "Transcriptional activation of hedgehog target genes in Drosophila is mediated directly by the cutius interruptus protein, a member of the GLI family of zinc finger DNA-binding proteins", Genes Dev., 19 (16): 2003-2013 (1996).					
AK	Bale, A., "Variable expressivity of patched mutations in flies and humans", Am. J. Human Genet., 60 (1): 10-12 (1997).					
AL	Bellusci, S. et al., "Involvement of Sonic hedgehog (Shh) in mouse embryonic lung growth and morphogenesis", Development, 124 (1): 53-63 (1997).					
AM	Bhat, K. and Schedl, P., "Requirement for engrailed and invected genes reveals novel regulatory interactions between engrailed/invected, patched, gooseberry and wingless during Drosophila neurogenesis", Development, 124 (9): 1675-1688 (1997).					
AN	Bitgood, M. et al., "Sertoli cell signaling by Desert hedgehog regulates the male germline", Curr. Biol., 6 (3): 298-304 (1996).					
AO	Bokor, P. et al., "The roles of hedgehog, wingless and lines in patterning the dorsal epidermis in Drosophila", Development, 122 (4): 1083-1092 (1996).					
AP	Bowie et al., "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions", Science 247: 1306-1310 (1990).					

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Sheets Page 2 of 16

INFORMATION DISCLOSURE CITATION IN AN APPLICATION <small>(use several sheets if necessary)</small>		Docket Number (Optional) CIBT-P10-203	Application Number 09/754,032
<i>OIC JC135</i>	<i>AUG 30 2001</i>	Applicant Scott et al.	
		Filing Date 03-Jan-2001	Group Art Unit 1646
		Cadigan, K. et al., "Localized expression of sloppy paired protein maintains the polarity of <i>Drosophila</i> parasegments", <i>Genes Dev.</i> , 8 (8): 899-913 (1994).	
	PATENT & TRADEMARK OFFICE	Chanut, F. and Heberlein, U., "Role of the morphogenetic furrow in establishing polarity in the <i>Drosophila</i> eye", <i>Development</i> , 121 (12): 4085-1094 (1995).	
	AR	Chavrier et al., "The complexity of the Rab and Rho GTP-binding protein subfamilies revealed by a PCR cloning approach", <i>Gene</i> 112: 261-264 (1992).	
	AS	Chen, E. et al., "Compartmental organization of the <i>Drosophila</i> genital imaginal disks", <i>Development</i> , 124 (1): 205-218 (1997).	
	AU	Chen, Y. et al., "Dual roles for patched in sequestering and transducing Hedgehog", <i>Cell</i> , 87(3): 553-563 (1996).	
	AV	Concordet, J. et al., "Spatial regulation of a zebrafish patched homologue reflects the roles of sonic hedgehog and protein kinase A in neural tube and somite patterning", <i>Development</i> , 122 (9): 2835-2846 (1996).	
	AW	Dhawan et al., "Systematic Delivery of Human Growth Hormone by Injection of Genetically Engineered Myoblasts", <i>Science</i> 254: 1509-1512 (1991).	
	AX	Dominguez, M. et al., "Sending and receiving the hedgehog signal: control by the <i>Drosophila</i> Gli protein cubitus interruptus", <i>Science</i> , 272 (5268): 1621-1625 (1996).	
	AY	Echelard, Y. et al., "Sonic hedgehog, a member of a family of putative signaling molecules, is implicated in the regulation of CNS polarity", <i>Cell</i> , 75: 1417-1430 (1993).	
	AY	Epps, J. et al., "Oroshigane, a new segment polarity gene of <i>Drosophila melanogaster</i> , functions in hedgehog signal transduction", <i>Genetics</i> 145 (4): 1041-1052 (1997).	
	BA	Epstein, D. et al., "Antagonizing cAMP-dependent protein kinase A in the dorsal CNS activates a conserved Sonic hedgehog signaling pathway", <i>Development</i> , 122 (9): 2884-2894 (1996).	
	BB	Forbes, A. et al., "The role of segment polarity genes during early oogenesis in <i>Drosophila</i> ", <i>Development</i> , 122 (10): 33283-3294 (1996).	
	BC	Gailani et al., "Developmental Genes and Cancer: Role of Patched in Basal Cell Carcinoma of the Skin", <i>J. Nat. Canc. Inst.</i> 89 (15): 1103-1109 (1997).	
	BD	Gailani, M. et al., "The role of the human homologue of <i>Drosophila</i> patched in sporadic basal cell carcinomas", <i>Nat. Genet.</i> , 14 (1): 78-81 (1996).	
	BE	Gomez-Skarmeta, J.L. et al. "Araucan and caupolican provide a link between compartment subdivisions and patterning of sensory organs and veins in the <i>Drosophila</i> wing", <i>Genes Dev.</i> , 10 (22): 2935-1945 (1996).	
	BF	Goodrich, L. et al., "Altered neural cell fates and medulloblastoma in mouse patched mutants", <i>Science</i> , 277 (5329): 1109-1113 (1997).	
	BG	Goodrich, L. et al., "Conservation of the hedgehog/patched signaling pathway from flies to mice: induction of a mouse patched gene by Hedgehog", <i>Genes Dev.</i> , 10 (3): 301-312 (1996).	

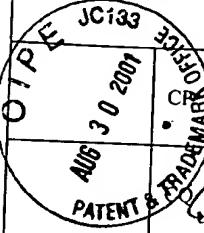
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		Applicant Scott et al.	
		Filing Date 03-Jan-2001	Group Art Unit 1646
O P E R A T I O N S JC133 AUG 30 2001 PATENT & TRADEMARK OFFICE	BH	Gorlin, R., "Nevoid basal-cell carcinoma syndrome", Medicine, 66: 98-113 (1987).	
	BJ	Grindley, J. et al., "Evidence for the involvement of the Gli gene family in embryonic mouse lung development", Dev. Biol., 188 (2): 337-348 (1997).	
	BK	Habuchi, et al., "Detailed deletion mapping of chromosome 9q bladder cancer: evidence for two tumour suppressor loci", Oncogene, 11:1671-1674 (1995).	
	BL	Hahn, H. et al., "A mammalian patched homolog is expressed in target tissues of sonic hedgehog and maps to a region associated with development abnormalities", J. Biol. Chem., 271 (21): 12125-12128 (1996).	
	BM	Heemskerk, J. et al., "Drosophila hedgehog acts as a morphogen in cellular patterning", Cell 76: 449-460 (1994).	
	BN	Hepker, J. et al., "Drosophila cubitus interruptus forms a negative feedback loop with patched and regulates expression of Hedgehog target genes", Development, 124 (2): 549-558 (1997).	
	BO	Hidalgo, A. and Ingham, P., "Cell patterning in the Drosophila segment: spatial regulation of the segment polarity gene patched", Development, 110: 291-301 (1990).	
	BP	Hooper et al., "The Drosophila patched gene encodes a putative membrane protein required for segmental patterning", Cell 59: 751-765 (1989).	
	BQ	Hynes, M., et al., "Control of cell pattern in the neural tube by zinc finger transcription factor and oncogene", Neuron 19(1): 1997.	
	BR	Ingham, "Hedgehog points the way", Curr. Biol. 4: 347-350 (1994).	
	BS	Ingham, P. et al., "Role of the Drosophila patched gene in positional signalling", Nature, 353: 184-187 (1991).	
	BT	Ingham, P. et al., "Quantitative effects of hedgehog and decapentaplegic activity on the patterning of the Drosophila wing", Curr. Biol., 5 (4): 432-440 (1995).	
	BU	Jensen, A. et al., "Expression of Sonic hedgehog and its putative role as a precursor cell mitogen in the developing mouse retina", Development, 124 (2): 363-371 (1997).	
	BV	Jiang, J. et al., "Protein kinase A and hedgehog signaling in Drosophila limb development", Cell, 80 (4): 563-572 (1995).	
	BW	Johnson, R. et al., "Patched overexpression alters wing disc size and pattern: transcriptional and post-transcriptional effects on hedgehog targets", Development, 121 (12): 4161-4170 (1995).	
	BX	Johnson, R. et al., "Human homolog of patched, a candidate gene for the basal cell nevus syndrome", Science, 272 (5268): 1668-1671 (1996).	
		Kalderon, D., "Morphogenetic signalling. Responses to hedgehog", Curr. Biol., 5 (6): 2279-2289 (1995).	

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INFORMATION DISCLOSURE CITATION IN AN APPLICATION <small>(use several sheets if necessary)</small>		Docket Number (Optional) CIBT-P10-203	Application Number 09/754,032
RECEIVED AUG 31 2001 TECH CENTER 1600/2900		Applicant Scott et al.	
		Filing Date 03-Jan-2001	Group Art Unit 1646
<p>Ato, Nippon Yakurigaku Zasshi, Folia Pharmacologica Japonica 102 (3): AN 94010590.</p> <p>Kojima, T. et al., "Induction of a mirror-image duplication of anterior wing structures by localized hedgehog expression in the anterior compartment of Drosophila melanogaster wing imaginal discs", Gene, 148 (2): 211-7 (1994).</p> <p>Krauss, S. et al., "A functionally conserved homolog of the Drosophila segment polarity gene hh is expressed in tissues with polarizing activity in zebrafish embryos", Cell, 75: 1431-1444 (1993).</p> <p>Lepage et al., "Signal transduction by cAMP-dependent protein kinase A in Drosophila limb patterning", Nature, 373 (6516): 711-715 (1995).</p> <p>Li, W., et al., "Function of protein kinase A in hedgehog signal transduction and Drosophila imaginal disc development", Cell, 80 (4): 553-562 (1995).</p> <p>Loftus, S., et al., "Murine model of Niemann-Pick C disease: mutation in a cholesterol homeostasis gene", Science, 277 (5323): 232-235 (1997).</p> <p>Ma, C. et al., "The segment polarity gene hedgehog is required for progression of the morphogenetic furrow in the developing Drosophila eye", Cell, 75 (5): 927-938 (1993).</p> <p>Ma, C. et al., "Wingless and patched are negative regulators of the morphogenetic furrow and can effect tissue polarity in the developing Drosophila compound eye", Development, 121 (8): 2279-2289 (1995).</p> <p>Ma et al., "Molecular Cloning and Characterization of rKlk10, a cDNA encoding T-Kininogenase from Rat Submandibular Gland and Kidney", Biochemistry 31: 10922-10928.</p> <p>Marigo, V. et al., "Biochemical evidence that patched is the Hedgehog receptor", Nature, 384 (6605): 176-179 (1996).</p> <p>Marigo, V. et al., "Conservation in hedgehog signaling: induction of a chicken patched homolog by Sonic hedgehog in the developing limb", Development, 122 (4): 1225-1233 (1996).</p> <p>Marigo, V. et al., "Sonic hedgehog differentially regulates expression of GLI and GLI3 during limb development", Dev. Biol., 180 (1): 273-283 (1996).</p> <p>Marigo, V. et al., "Regulation of patched by sonic hedgehog in the developing neural tube", Proc. Natl. Acad. Sci. USA, 93(18): 9346-9351 (1996).</p> <p>Nakamura, T. et al., "Induction of osteogenic differentiation by hedgehog proteins", Biochem. Biophys. Res. Comm., 237 (2): 465-469 (1997).</p> <p>Nakano, Y. et al., "A protein with several possible membrane-spanning domains encoded by the Drosophila segment polarity gene patched", Nature, 341: 508-513 (1989).</p> <p>Nusse, R. "Patching up Hedgehog", Nature, 384 (6605): 119-120 (1996).</p> <p>Oro, A. et al., "Basal cell carcinomas in mice overexpressing sonic hedgehog", Science, 276(5313): 817-821 (1997).</p>			

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Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i>		Docket Number (Optional) CIBT-P10-203	Application Number 09/754,032
		Applicant Scott et al.	
		Filing Date 03-Jan-2001	Group Art Unit 1646
Pennisi, "Gene Linked to Commonest Cancer", Science 272: 1583-1584 (1996).			
CR	325	Perrimon et al., "Generating lineage-specific markers to study Drosophila development", Dev. Genet. 12:238-252 (1991).	
CR	325	Perrimon, N., "Serpentine proteins litter into the wingless and hedgehog fields", Cell, 86 (4): 513-516 (1996).	
CS	325	Phillips, R. et al., "The Drosophila segment polarity gene patched is involved in a position signalling mechanism in imaginal discs", Development, 110: 105-114 (1990).	
CT	325	Quinn, A. et al., "Chromosome 9 allele loss occurs in both basal and squamous cell carcinomas of the skin", J. Inves. Dermatology, 102: 300-303 (1994).	
CU	325	Quinn, A. et al., "Delineation of two distinct deleted regions on chromosome 9 in human non-melanoma skin cancers", Genes, Chromosomes & Cancers, 11:222-225 (1994).	
CV	325	Riddle, R. et al., "Sonic hedgehog mediates the polarizing activity of the ZPA", Cell, 75: 1401-1416 (1993).	
CW	325	Roelink, H. et al., "Floor plate and motor neuron induction by <i>vhh-1</i> , a vertebrate homolog of hedgehog expressed by the notochord", Cell, 76: 761-775 (1994).	
CX	325	Rogers, G. et al., "Patched gene mutation screening in patients with basal cell nevus syndrome using bidirectional dideoxy fingerprinting", J. Invest. Dermatol. Abstracts, 108(4): 598, # 364, (1997).	
CY	325	Roush, W., "Hedgehog's patterning call is patched through, smoothly", Science, 274 (5291): 1304-1305 (1996).	
CZ	325	Sanicola, M. et al., "Drawing a stripe in Drosophila imaginal disks: negative regulation of decapentaplegic and patched expression by engrailed", Genetics, 139 (2): 745-756 (1995).	
DA	325	Schuske, K. et al., "Patched overexpression causes loss of wingless expression in Drosophila embryos", Dev. Biol., 164 (1): 300-301 (1994).	
DB	325	Shilo, B., "Tumor suppressors. Dispatches from patched", Nature, 382 (6587): 115-116 (1996).	
DC	325	Simcox, A. et al., "Imaginal discs can be recovered from culture embryos mutant for the segment-polarity genes engrailed, naked and patched but nor from wingless", Development, 107: 715-722 (1989).	
DD	325	Sisson, J. et al., "Costal2, a novel kinesin-related protein in the Hedgehog signaling pathway", Cell, 90 (2): 235-245 (1997).	
DE	325	Smith et al., "Genes Transferred by Retroviral Vectors into Normal and Mutant Myoblasts in Primary Cultures Are Expressed in Myotubes", Mol. Cell. Biol. 3268-3271 (1990).	
DF	325	Spradling et al., "Transposition of Cloned P Elements into Drosophila Germ Line Chromosomes", Science 218: 341-347 (1982).	

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		Stone, D. et al., "The tumor-suppressor gene patched encodes a candidate receptor for Sonic hedgehog", Nature, 384 (6605): 129-132 (2000).	
		Struhl, G. et al., "Hedgehog acts by distinct gradient and signal relay mechanisms to organize cell type d cell polarity in the Drosophila abdomen", Development, 124 (11): 2155-2165 (1997).	
DI		Strutt, D. et al., "Ommatidial polarity in the Drosophila eye is determined by the direction of furrow progression and local interactions", Development, 121 (12): 4247-4256 (1995).	
DJ		Strutt, D. et al., "Regulation of furrow progression in the Drosophila eye by cAMP-dependent protein kinase A", Nature, 373 (6516): 705-709 (1995).	
DK		Tabata, T. et al., "The Drosophila hedgehog gene is expressed specifically in posterior compartment cells and is a target of engrailed regulation", Genes Dev., 6(12B): 2635-2645 (1992).	
DL		Tabata, T. et al., "Hedgehog is a signaling protein with a key role in patterning Drosophila imaginal discs", Cell, 76: 89-102 (1994).	
DM		Takabatake, T. et al., "Hedgehog and patched gene expression in adult ocular tissues", FEBS Letters, 410 (2-3): 485-489 (1997).	
DN		Thummel, C. et al., "Vectors for Drosophila P-element mediated transformation and tissue culture transfection", Gene, 74: 445-446 (1988).	
DO		Von Ohlen, T. et al., "Hedgehog signaling regulates transcription through cubitus interruptus, a sequence-specific DNA binding protein", Proc. Natl. Acad. Sci. USA, 94 (6): 2404-2409 (1997).	
DP		Vorechovsky, I. et al., "Somatic mutations in the human homologue of Drosophila patched in primitive neuroectodermal tumors", Oncogene, 15 (3): 361-366 (1997).	
DQ		Vortkamp, A., et al., "Regulation of rate of cartilage differentiation by Indian hedgehog and PTH-related protein", Science, 273 (5275): 613-622 (1996).	
DR		Watson, J., Recombinant DNA, W. H. Freeman and Co., New York, 363, (1992).	
DS		Wickings, C. et al., "Fine genetic mapping of the gene for nevoid basal cell carcinoma syndrome", Genomics, 22: 505-511 (1994).	
EXAMINER		DATE CONSIDERED	
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.			

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